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New Food Additives (2-Ethyl-5-methylpyrazine and 2 other chemicals)

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On February 3, 2010, the Government of Japan announced it would designate three new food additives: 2-Ethyl-5-methylpyrazine, Isopentylamine and Magnesium silicate. The domestic comment period will close on February 17, 2010 however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject.

General Information:

On February 3, 2010, the Japanese Government announced plans to designate three new food additives, 2-Ethyl-5-methylpyrazine, Isopentylamine and Magnesium silicate.

Please note that the use of Magnesium silicate in the announcement is limited as filtration aid. The

domestic comment period will close on February 17, 2010 however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject.

Comments can be either English or Japanese. When you submit comments, please send them directly to the Japanese Government at:

Ms. M. ISOZAKI (isozaki-makiko@mhlw.go.jp)

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Tel. ex. 2453

Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Designation of Food Additives

Purpose and background

The Ministry of Health, Labour and Welfare is going to newly designate three substances as authorized food additives.

Under Article 10 of the Food Sanitation Law, food additives can be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. When use standards or compositional specifications are established for food additives based on Article 11 of the law, those additives are not permitted to be used or marketed unless they meet these standards or specifications.

In response to a request from the Minister, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the authorization of the three substances (2-Ethyl-5-methylpyrazine, Isopentylamine, and Magnesium Silicate). The subcommittee has concluded as follows.

of conclusion

The Minister should designate 2-Ethyl-5-methylpyrazine, Isopentylamine, and Magnesium Silicate, based on Article 10 of the Food Sanitation Law, as food additives unlikely to harm human health and establish compositional specifications and other necessary standards for these substances, based on Article 11 of the law (see Attachments 2-1, 2-2, and 2-3).

Additional Information

Progress in the designation procedure of food additives that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan (Attachment 2-4).

Attachment 2-1

2-Ethyl-5-methylpyrazine **2-エチル-5-メチルピラジン**

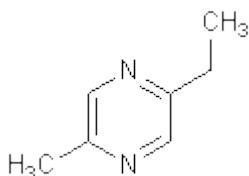
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 2-Ethyl-5-methylpyrazine

Structural formula



Molecular formula C₇H₁₀N₂

Mol. Weight 122.17

Chemical name, CAS number 2-Ethyl-5-methylpyrazine [13360-64-0]

Content 2-Ethyl-5-methylpyrazine contains not less than 95.0% of 2-ethyl-5-methylpyrazine (C₇H₁₀N₂).

Description 2-Ethyl-5-methylpyrazine occurs as a colorless to light yellow, transparent liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of 2-Ethyl-5-methylpyrazine, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

Purity

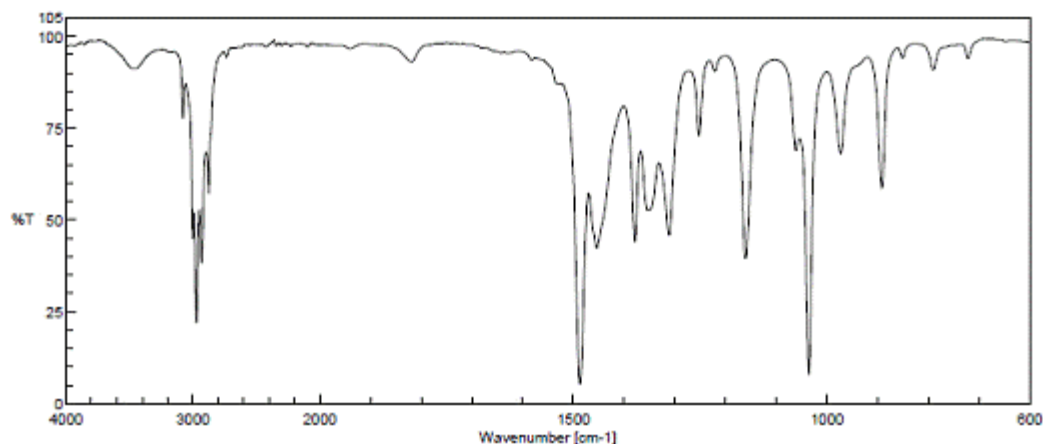
(1) Refractive index n_D^{20} : 1.491–1.501.

(2) Specific gravity d_4^{25} : 0.960–0.970.

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (1). Use a silicate-glass capillary tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 mm thick layer of polyethylene glycol for gas chromatography.

Reference Spectrum

2-Ethyl-5-methylpyrazine



Attachment 2-2

Isopentylamine イソペンチルアミン

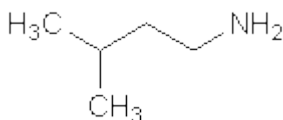
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 3-Methyl-1-butanamine, Isopentylamine, Isoamylamine

Structural formula



Molecular formula $\text{C}_5\text{H}_{13}\text{N}$

Mol. Weight 87.16

Chemical name, CAS number 3-Methylbutylamine [107-85-7]

Content Isopentylamine contains not less than 98.0% of isopentylamine ($\text{C}_5\text{H}_{13}\text{N}$).

Description Isopentylamine occurs as a colorless to light yellow, transparent liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of Isopentylamine, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

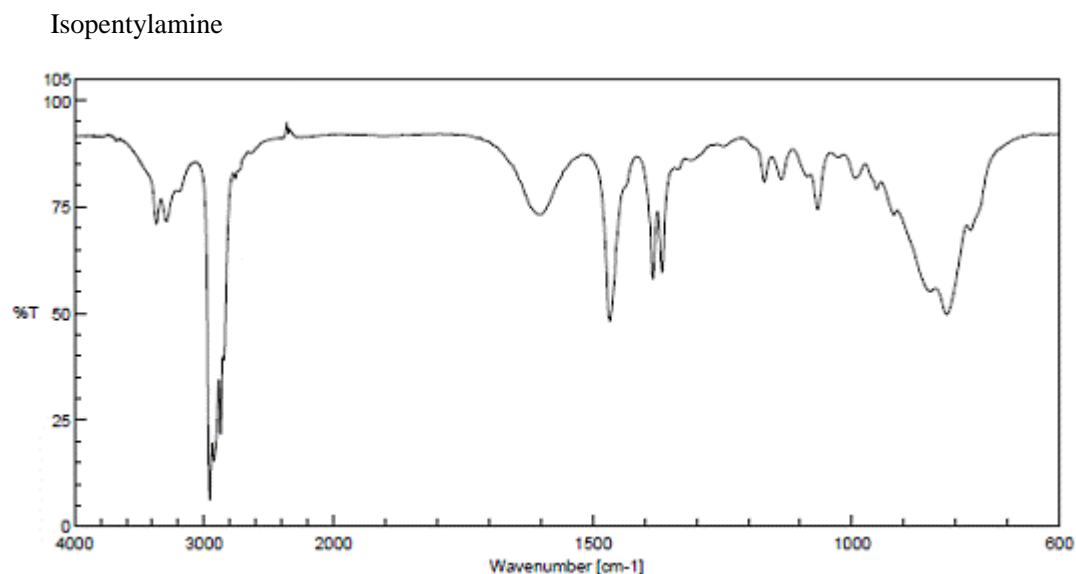
Purity

(1) Refractive index n_D^{20} : 1.405–1.411.

(2) Specific gravity 0.747–0.753.

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2). Use a silicate-glass capillary tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 mm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum



Attachment 2-3

Magnesium Silicate

ケイ酸マグネシウム

Standard for use

It shall not be used for uses other than a filtration aid for fats and oils. It shall be removed before the completion of the final product.

Compositional specifications

Substance name Magnesium Silicate

Chemical name, CAS number Magnesium silicate [1343-88-0]

Definition Magnesium Silicate is a synthetic compound manufactured by the precipitation reaction between sodium silicate and a soluble magnesium salt. Its composition is in a molar ratio of magnesium oxide to silicon dioxide of approximately 2 to 5.

Content Magnesium Silicate, when calculated on the ignited basis, contains the equivalent of not less than 15.0% of magnesium oxide ($\text{MgO} = 40.30$) and the equivalent of not less than 67.0% of silicon dioxide ($\text{SiO}_2 = 60.08$).

Description Magnesium Silicate occurs as a white, odorless, fine powder.

Identification

(1) Mix 0.5 g of Magnesium Silicate with 10 ml of dilute hydrochloric acid, and filter the mixture. The filtrate neutralized with ammonia TS responds to the test for Magnesium Salt in the Qualitative Tests.

(2) Prepare a bead by fusing a few crystals of ammonium sodium hydrogenphosphate tetrahydrate on a platinum loop in the flame of a Bunsen burner. Place the hot, transparent bead in contact with Magnesium Silicate, and fuse again. An unfused lump floats about in the bead, and when cooled, the bead becomes opaque producing a web-like

pattern.

Purity

(1) pH 7.0–11.0 (10% suspension).

(2) Water-soluble substances Not more than 3%.

Weigh accurately about 10 g of Magnesium Silicate in a beaker, add 150 ml of water, cover the beaker with a watch glass, and boil gently for 15 minutes. Cool, replenish the lost water, and allow the mixture to stand for 15 minutes. Filter through a filter paper for quantitative analysis (5C) by suction. If the filtrate is turbid, repeat the filtration until the clear filtrate is obtained. Add water to exactly 75 ml of the filtrate to make exactly 100 ml. Refer the resulting solution to as solution A. Transfer exactly 50 ml of solution A into a tared platinum dish, evaporate to dryness, and ignite for 3 hours at 450–550°C. Cool, and weigh the dish with the residue. Determine the residue.

(3) Free alkali Not more than 1% as NaOH.

Add 2 drops of phenolphthalein TS to 20 ml of solution A, and add 0.1 mol/L hydrochloric acid until the color of the solution disappears. The consumption of the hydrochloric acid is not more than 2.5 ml.

(4) Fluoride Not more than 10 mg/g as F.

Test Solution Weigh exactly 2.0 g of Magnesium Silicate in a polyethylene beaker, add 60 ml of water, and stir the mixture for 15 minutes. Transfer the suspension into a 100-ml volumetric flask, and add water to volume. Centrifuge 50 ml of the resulting suspension at 5,000 rpm for 15 minutes, transfer exactly 20 ml of the supernatant into a polyethylene beaker, and add 10 ml of EDTA–tris TS.

Control Solution Weigh exactly 2.210 g of sodium fluoride, previously dried at 110°C for 2 hours, in a polyethylene beaker, and dissolve in 200 ml of water with stirring. Transfer this solution into a 1,000-ml polyethylene volumetric flask, and add water to volume. Use the resulting solution as the control stock solution. Store the stock solution in a polyethylene bottle. Prepare a control solution fresh before use by the following procedure. Place exactly 2 ml of the control stock solution in a 1,000-ml volumetric flask, and dilute with water to volume. Transfer exactly 5 ml of this solution into a 50-ml volumetric flask, and dilute with water to volume. Place exactly 20 ml of the second solution in a polyethylene beaker, and add 10 ml of EDTA–tris TS.

Procedure Measure the electric potentials using a potentiometer connected to a reference electrode and a fluoride ion electrode. The potential of the test solution is not less than that of the control solution.

(5) Lead Not more than 5.0 mg/g as Pb.

Test Solution Weigh exactly 5.0 g of Magnesium Silicate into a beaker, add 50 ml of diluted hydrochloric acid solution (1 in 4), and stir. Cover with a watch dish, and boil gently for 15 minutes. Filter this solution by suction through a quantitative filter paper (5C) into a 50-ml volumetric flask. Rinse the beaker and the residue on the filter paper with hot water, and add the filtrate and washings to the flask. Cool, and add diluted hydrochloric acid solution (1 in 4) to make exactly 50 ml.

Control Solution To exactly 5 ml of Lead Standard Solution, add diluted hydrochloric acid (1 in 4) to make 100 ml.

Procedure Determine the absorbances of the test solution and control solution by flame atomic absorption spectrophotometry using the operating conditions given below. The absorbance of the test solution is not more than that of the control solution.

Operating conditions

Light source: Lead hollow cathode lamp.

Analytical line wavelength: 217 nm.

Supporting gas: Air.

Combustible gas: Acetylene.

(6) Arsenic Not more than 4.0 mg/g as As₂O₃.

Test Solution Add 5 ml of diluted hydrochloric acid (1 in 4) to 0.50 g of Magnesium Silicate, and heat gently while agitation until boiling. Cool immediately, centrifuge the mixture at 3,000 rpm for 5 minutes, and collect the supernatant. To the residue, add 5 ml of diluted hydrochloric acid (1 in 4), agitate, centrifuge, and collect the washings. Add 10 ml of water to the residue, and proceed in the same manner. Combine all washings with the collected supernatant, and evaporate to 5 ml by heating on a water bath.

Apparatus Use Apparatus B.

Loss on Drying Not more than 15% (105°C, 2 hours).

Residue on Ignition Not more than 15% (dried sample, 900–1000°C, 20 minutes).

Assay

(1) Magnesium oxide To accurately weighed about 1.5 g of Magnesium Silicate, add exactly 50 ml of 0.5 mol/L sulfuric acid, and heat on a water bath for 1 hour. Cool the mixture to room temperature, add methyl orange TS, and titrate the excess acid with 1 mol/L sodium hydroxide. Calculate the magnesium oxide content on the ignited basis.

Each ml of 0.5 mol/L sulfuric acid = 20.15 mg of MgO

(2) Silicon dioxide Weigh accurately about 0.7 g of magnesium Silicate in a beaker, add 20 ml of diluted sulfuric acid (3 in 100), and heat on a water bath for 90 minutes. Filter the supernatant by suction using a filter holder equipped with a membrane filter (0.1 mm pore size). Add 10 ml of hot water to the beaker containing the residue, stir, and filter the supernatant by decantation through the membrane filter. Wash the residue twice with 10 ml of hot water each time, and decant each supernatant onto the filter. To the residue, add 25 ml of water, heat on a water bath for 15 minutes, and transfer the residue onto the membrane filter. Wash the residue with hot water until the washings no longer respond to test (1) for Sulfate in the Qualitative Tests. Heat the residue with the membrane filter in a platinum crucible to dryness, incinerate, and ignite for 30 minutes. Cool, and weigh (W_1 g). Moisten the residue with water, add 6 ml of hydrofluoric acid and 3 drops of sulfuric acid, evaporate to dryness, and ignite for 5 minutes. Cool, and weigh (W_2 g). Determine the silicon dioxide content by the formula:

$$\text{Content (\% of silicon dioxide (SiO}_2\text{))} = \frac{W_1 - W_2}{\text{Weight (g) of the sample on the ignited basis}} \times 100$$

Reagent

Ammonium Sodium Hydrogenphosphate Tetrahydrate [K9013:2002] White crystals or granules. Easily effloresce in air.

Identification (1) Add 1 ml of silver nitrate solution of (1 in 50) to 5 ml of a solution of Ammonium Sodium Hydrogenphosphate Tetrahydrate (1 in 20). A yellow precipitate is produced. The precipitate dissolves when 1 ml of diluted nitric acid (1 in 3) or 5 ml of ammonia solution (2 in 5) is added.

(2) Add 1 ml of sodium hydroxide solution (1 in 10) to 5 ml of a solution of Ammonium Sodium Hydrogenphosphate Tetrahydrate (1 in 20), and heat. Ammonia is evolved.

(3) A solution of Ammonium Sodium Hydrogenphosphate Tetrahydrate (1 in 20) responds to test (1) for Sodium Salt in the Qualitative Tests.

Purity Clarity of solution Clear (1.0 g, water 20 ml).